In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 21-0685V

SONJA JACKMAN,

Chief Special Master Corcoran

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Filed: July 8, 2024

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.

Alec Saxe, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On January 12, 2021, Sonja Jackman filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). More than a year later, on February 18, 2022, she filed an amended petition, containing additional detail and medical record citations. ECF No. 26. Petitioner alleges that she suffered a right shoulder injury related to vaccine administration ("SIRVA"), a defined Table injury, after receiving an influenza ("flu") vaccine on November 4, 2020. Amended Petition at 1-2, 9.

¹ Because this Fact Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Fact Ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

For the reasons discussed below, I find the onset of Petitioner's right shoulder pain occurred within 48 hours of vaccination. I also find Petitioner suffered the residual effects of the right shoulder pain she experienced post-vaccination for more than six months.

I. Relevant Procedural History

Presumably due to the then-anticipated removal of SIRVA from the Vaccine Table,³ Ms. Jackman filed a cursory petition without medical records on January 12, 2021. ECF No. 1. Over the subsequent 13-month period, she filed two signed declarations⁴ and the medical records required under the Vaccine Act. Exhibits 1-11, ECF Nos. 7, 11, 16, 20, 22; see Section 11(c). She also filed an amended petition containing additional details and medical records citation. ECF No. 26. On June 2, 2022, the case was activated and assigned to the "Special Processing Unit" (the "SPU" - OSM's adjudicatory system for resolution of cases deemed likely to settle). ECF No. 27.

Thereafter, Petitioner continued to file updated medical records. Exhibits 12, filed Apr. 26, 2023, ECF No. 32. Per my instruction, she also worked to finalize a demand. Status Reports, filed Mar. 20 and May 23, 2023, ECF Nos. 31, 34.

On August 7, 2023, Respondent filed his Rule 4(c) Report, opposing compensation. ECF No. 36. Emphasizing Petitioner's statements - made when first seeking treatment on December 2, 2020, only 28-days post-vaccination, that her right shoulder pain began more than one month ago and that her pain was exacerbated by the flu vaccine, Respondent argued that Petitioner is unable to satisfy the first, second, and fourth Qualifications and Aids to Interpretation ("QAI") criteria. *Id.* at 8-9; see 42 C.F.R. § 100.3(c)(10)(i)(ii) & (iv) (requiring pain onset within 48 hours of vaccination and no prior shoulder pain, inflammation, or dysfunction or current condition that would explain her symptoms). He also maintained Petitioner cannot satisfy the Vaccine Act's six-month severity requirement because she attended her physical therapy ("PT") session approximately two weeks shy of the six-month mark and did not return for treatment until almost eight months thereafter. Rule 4(c) Report at 9; Section 11(c)(1)(D)(i) (statutory six-month severity requirement). The matter is now ripe for adjudication.

2

³ On July 20, 2020, the Secretary of Health and Human Services proposed the removal of SIRVA from the Vaccine Injury Table. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Proposed Rule, 85 Fed. Reg. 43794 (July 20, 2020). On April 22, 2021, the final rule removing SIRVA from the Vaccine Table was rescinded. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Withdrawal of Final Rule, 86 Fed. Reg. 21209 (Apr. 22, 2021).

⁴ Although not notarized, the declarations were signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 10-11.

II. Issues

At issue is whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours, as required by the Vaccine Injury Table and QAI for a Table SIRVA, and whether Petitioner continued to suffer the residual effects of the SIRVA for more than six months. 42 C.F.R. § 100.3(a) XIV.B. (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI); Section 11(c)(1)(D)(i) (statutory six-month severity requirement).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events

when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Findings of Fact

I make these findings, related to onset and severity, after a complete review of the record to include all medical records, affidavits, briefing, and additional evidence filed. Specifically, I base the findings on the following evidence:

Prior to vaccination, Petitioner (a photographer) suffered from common conditions: hypertension (accompanied by headaches and some vertigo), anxiety, depression, and gastroesophageal reflux disease. Exhibit 2. In 2018-19, she experienced a painful bump on her right wrist, diagnosed as right wrist ganglion and requiring surgery in late June 2019. *Id.* at 23-32; Exhibit 4. In late November 2019, Petitioner visited an urgent care facility

for pain in her right ear and an itchy rash on her right upper arm, chest, right jaw, and leg. Exhibit 3 at 15. In May 2020, she visited a different urgent care facility for right wrist and thumb pain after hitting her hand on something. Exhibit 7 at 6.

- On November 4, 2020, Petitioner (52 years old) received the flu vaccine intramuscularly in her right arm at a Sam's Club. Exhibit 1 at 3.
- On December 2, 2020, 28-days post-vaccination, Petitioner visited her primary care provider ("PCP") complaining of "1 month of right arm pain, decreased rom, stabbing pain anytime she moves it." Exhibit 2 at 61. Characterized as a "new problem," her symptoms were noted to include myalgias "[e]xacerbated by: the flu vaccine." *Id.* Multiple entries in this medical record, including the entry pertaining to the PCP's diagnosis, describe Petitioner as suffering from "immobility and pain for one month after the flu vaccine". *Id.* at 59; accord. *id.* at 62-63, 65-66, 68. The orthopedist ordered a CT and vascular upper venous right arm testing, prescribed cyclobenzaprine for muscle spasms and meloxicam, and referred Petitioner to an orthopedist. *Id.* at 70.
- Performed one week later, the CT scan revealed "[n]onspecific ill-defined hyperdensity along the distal teres minor tendon/muscle" prompting consideration of hyperemia⁵ and tendinitis, and a suggestion of cholelithiasis.⁶ Exhibit 5 at 11. The duplex ultrasound showed no evidence of deep vein thrombosis. *Id.* at 26.
- On December 16, 2020, Petitioner was seen by the orthopedist for "evaluation of right should pain." Exhibit 6 at 11. Reporting that [s]he has had trouble with the shoulder now for 6 weeks . . . [and] pain develop[ed] after she received a flu shot," Petitioner described sharp pain (at a level of seven out of ten), primarily in the posterior and lateral aspects, and sometimes radiating towards her neck, that worsened with motion. *Id.* After reviewing x-ray results which were unremarkable, the orthopedist administered a steroid injection and recommended activity modification. *Id.* at 12.

5

⁵ Hyperemia is "an increase of blood in a part." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ("DORLAND'S") at 888 (32th ed. 2012).

⁶ Cholelithiasis is "the presence or formation of gallstones." DORLAND'S at 349.

- On February 2, 2021, Petitioner underwent an MRI of her right shoulder that
 revealed "[m]oderate distal insertional teres minor... tendinosis with strain
 of the distal insertional muscle fibers, [m]ild supraspinatus and infraspinatus
 tendinosis," "[m]ild acromioclavicular and minor glenohumeral arthrosis,"
 and no rotator cuff tear, muscle atrophy, or "significant joint effusion or
 subacromial/subdeltoid bursitis." Exhibit 6 at 13.
- Almost two weeks later, Petitioner returned to the orthopedist, reporting that her steroid injection did not provide "much relief." Exhibit 6 at 10. Observing pain along the posterior lateral aspect with palpitation full, but painful, ROM, and "weakness secondary to pain," the orthopedist prescribed an oral steroid and recommended physical therapy ("PT"). Id.
- On March 4, 2021, Petitioner attended her first PT session. Exhibit 8 at 35-39. She again linked her right shoulder pain to the flu vaccine, reporting "pain after receiving a Flu shot." *Id.* at 36. Estimating her pain level as six to nine out of ten, Petitioner was assessed as having a DASH score of 86. *Id.*
- By her fifth PT session on March 23, 2021, Petitioner's pain had decreased to three at rest and five at worst. Exhibit 8 at 24. Her DASH score was noted to be 84. *Id.* at 23-24.
- At her seventh PT session on April 6, 2021, Petitioner reported that "she feels the exercise pushing [her] shoulder back is helping improve her motion, but she still has 'achiness' inside her shoulder." Exhibit 8 at 18. The therapist opined that Petitioner's "[g]oals remain appropriate and can be met with additional therapy," twice weekly. *Id.* at 19.
- At her eighth and last PT session on April 21, 2021, Petitioner stated that she had not been to PT because she was in Michigan visiting her mother. Exhibit 8 at 15. Reporting that she had continued her exercises on her own, she described her shoulder as "not any worse," adding that "she is still having some pain along the outside top of [her] shoulder when she lowers [her] arm from [a] raise[d] position." *Id.* Noting that Petitioner "did well with new exercises," but that needed to modify one exercise to avoid increased pain, the therapist again opined that Petitioner would benefit from continued PT. *Id.*
- Petitioner did not seek medical treatment again until December 8, 2021, when she was seen for follow-up of several ongoing conditions, including right shoulder tendinitis. Exhibit 9 at 13-35. Regarding her shoulder, she

reported "[d]ifficulty holding things if she role [sic] on it at night." *Id.* at 17. The PCP prescribed Gabapentin for her pain and instructed her to return for a physical in six months.

- As instructed, Petitioner returned to her PCP on June 8, 2022. Exhibit 12 at 9-26. Her primary concern at this appointment was abdominal pressure and abnormal stools. *Id.* at 13-14. Although than a notation that her ROM was normal under "Musculoskeletal", there was no discussion of Petitioner's right shoulder tendinitis. *Id.* at 16. However, it appears the PCP ordered a refill of her Gabapentin and instructed Petitioner to follow-up with the orthopedist. *Id.* at 12.
- Petitioner's PCP medical records contain an entry stating her prescription for Gabapentin was discontinued on July 19, 2022. Exhibit 12 at 11.
- In her first declaration, signed under penalty of perjury on February 12, 2021, Petitioner addressed the basic requirement of a vaccine claim: that neither she nor any other party has filed a civil action or received an award for her SIRVA. Exhibit 11.
- In her second declaration, signed under penalty of perjury on February 16, 2022, Petitioner provided more details regarding her alleged SIRVA. Exhibit 10. She recounted that she "noticed that something felt different almost immediately after the injection." *Id.* at ¶ 2. She added that "the pain spread through [her] chest, under [her] breast plate." *Id.* at ¶ 3. "Over the next several days, the chest pain resolved, but the pain in [her] right shoulder remained." *Id.* Petitioner also provided detailed descriptions of the effects of her injury. *Id.* at ¶¶ 9-11.

Onset

The record as a whole supports Petitioner's description of immediate pain upon vaccination. In multiple post-vaccination medical records involving her PCP, orthopedist, and physical therapist, Petitioner consistently reported right shoulder pain that began upon vaccination. Exhibit 2 at 59; Exhibit 6 at 11; Exhibit 8 at 36. Without fail, she attributed her injury to the flu vaccine she received in early November 2020. *Id.* While these entries were based upon information provided by Petitioner, they still should be afforded greater weight than more current representations, as they were uttered contemporaneously with Petitioner's injury for the purposes of obtaining medical care.

The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that greater weight should be accorded to this information even when the information is provided by a patient (such that it could still be somewhat subjective).

The basis for Respondent's onset challenge is found in two entries contained in the medical record from Petitioner's December 2, 2020 visit to her PCP, when she first sought treatment of her right shoulder pain. The first entry states that Petitioner's shoulder pain began one month ago. Exhibit 2 at 61. If considered to equate to exactly 30 days (the length of the month of November), this entry would place Petitioner's pain onset two days *prior* to vaccination. The second entry states that the vaccine exacerbated Petitioner's symptoms. *Id.*

However, the record in this case also contains multiple entries clearly stating that Petitioner's symptoms began after vaccination. Exhibit 2 at 59, 62-63, 65-66, 68. And the entry referring to the exacerbation of Petitioner's symptoms appears to be a standard entry utilized by the PCP. Furthermore, the term "one month" is not an exact or consistent term, and is often used to describe a time period slightly more of less than 30 days. Thus, I do not find Respondent's arguments related to pain onset to be persuasive.

Accordingly, I find there is preponderant evidence to establish the onset of Petitioner's pain occurred within 48 hours of vaccination. Specifically, I find Petitioner's pain began immediately upon vaccination as Petitioner alleges.

Severity

To satisfy the Vaccine Act's severity requirement in this case, Petitioner must show that she suffered symptoms of her alleged SIRVA beyond May 4, 2021 (assuming an immediate onset on November 4th, which I find the record preponderantly supports). The above medical entries clearly establish that Petitioner continued to suffer right shoulder pain on April 21, 2021, less than two weeks shy of the six-month mark. At that PT session, she reported symptoms that had not worsened, but also had not resolved, while she relied on home exercises only during a visit to her mother. Exhibit 8 at 15. The therapist reported the need to modify one exercise which caused Petitioner increased pain and opined that she would benefit from further PT. *Id.*

Although Petitioner did not pursue any additional PT, she also did not received treatment likely to have resulted in a quick resolution of the symptoms she reported in

late April 2021, such as a steroid injection. Considering the rate of her progress up unto that point, it is reasonable to infer that Petitioner continued to experience symptoms, at least through May 4, 2021, only 13 days later.

Additionally, Petitioner again reported at least some mild symptoms when seen by her PCP in December 2021. And she attended no intervening appointments prior to that time. The mild and intermittent nature of the symptoms Petitioner described in December 2021, does not prevent her from satisfying the severity requirement. Thus, I find there is preponderant evidence to establish Petitioner suffered the residual effects of her alleged SIRVA for more than six months.

V. Scheduling Order

Because Respondent based his remaining objections to compensation upon his mistakenly belief that the evidence preponderantly supported a pain onset prior to vaccination, which I have found not to be accurate, I am allowing him the opportunity to provide his current position in light of my findings related to pain onset and severity. Additionally, Petitioner should provide Respondent with a reasonable demand and supporting documentation.

Respondent shall file a status report indicating how he intends to proceed in light of my factual ruling by no later than <u>Friday</u>, <u>August 09</u>, <u>2024</u>. In the status report, he also should indicate whether Petitioner has provided him with a demand.

IT IS SO ORDERED.

<u>s/Brian H. Corcoran</u>

Brian H. Corcoran Chief Special Master